



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA- 2012-P-1071]

Determination That GEREf (Sermorelin Acetate) Injection, 0.5 Milligrams Base/Vial and 1.0 Milligrams Base/Vial, and GEREf (Sermorelin Acetate) Injection, 0.05 Milligrams Base/Amp, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that GEREf (Sermorelin Acetate) injection, 0.5 milligrams (mg) base/vial and 1.0 mg base/vial, and GEREf (Sermorelin Acetate) injection, 0.05 mg base/amp, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for GEREf (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, and GEREf (Sermorelin Acetate) injection, 0.05 mg base/amp, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure.

ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GEREF (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, is the subject of NDA 20-443, held by EMD Serono, and initially approved on September 26, 1997; and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, is the subject of NDA 19-863, held by EMD Serono, and initially approved on December 28, 1990. GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, is indicated for the treatment of idiopathic growth hormone deficiency (GHD) in children with growth failure, and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, is indicated for evaluating the ability of the somatotroph of the pituitary gland to secrete growth hormone.

In a letter dated December 2, 2008, EMD Serono notified FDA that GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, was being discontinued and requested withdrawal of NDA 20-443; and FDA moved that drug product to the “Discontinued Drug Product List” section of the Orange Book. In a letter dated July 11, 2008, EMD Serono also notified FDA that GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book as well. In addition, in a letter dated December 12, 2008, EMD Serono requested withdrawal of NDA 19-863 for GERE (Sermorelin Acetate) injection, 0.05 mg base/amp. In the Federal Register of May 19, 2009 (74 FR 23407), FDA announced that it was withdrawing approval of NDA 19-863 and NDA 20-443, effective June 18, 2009.

Alvin J. Lorman submitted a citizen petition dated October 12, 2012 (Docket No. FDA-2012-P-1071), under 21 CFR 10.30, requesting that the Agency determine whether GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, was withdrawn from the market for reasons of safety and efficacy. Although the citizen petition did not request that we determine whether GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, approved under

NDA 19-863, was withdrawn for safety or efficacy, that product has also been discontinued. On our own initiative, we have also determined whether GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events for both GERE products. We have reviewed the available evidence and determined that both GERE products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to GERE (Sermorelin Acetate) injection, 0.5 mg base/vial and 1.0 mg base/vial, and GERE (Sermorelin Acetate) injection, 0.05 mg base/amp, may be approved by the Agency as long as

they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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